IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI WESTERN DIVISION

DONNA GUILFORD,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 4:19-CV-00955-DGK
	)	
BOSTON SCIENTIFIC CORPORATION,	)	
	)	
Defendant.	)	

ORDER GRANTING IN PART DEFENDANT'S MOTION TO DISMISS

This products-liability action arises out of Plaintiff Donna Guilford's injuries after being implanted with two of Defendant Boston Scientific Corporation's surgical-mesh products, Pinnacle Pelvic Floor Repair Kit (the "Pinnacle") and Obtryx Mid-Urethral Sling (the "Obtryx Sling" and collectively with the Pinnacle, the "Products"). Now before the Court is Defendant's motion to dismiss (Doc. 9). For the reasons below, the motion is GRANTED IN PART.

Background

For purposes of resolving the pending motion, the relevant allegations in Plaintiff's complaint are summarized as follows. In the late 2000s, Plaintiff suffered from cystocele and stress urinary incontinence. To treat those conditions, Dr. Willis Kephart at Lafayette Regional Heath Center in Lexington, Missouri, surgically implanted Plaintiff with the Pinnacle and the Obtryx Sling in 2009. The Products are both surgical-mesh devices containing monofilament polypropylene mesh that are manufactured, packaged, labeled, marketed, sold, and distributed by Defendant as treatments for stress urinary incontinence and cystocele. In the years after being implanted, Plaintiff began experiencing pain and had the Products removed in 2018. She alleges she has sustained injuries to the pelvic-region and deformities that will require future corrective surgeries.

Plaintiff brought this lawsuit in November 2019, alleging seven causes of action: (1) negligence; (2) strict liability—design defect; (3) strict liability—manufacturing defect; (4) strict liability—failure to warn; (5) breach of warranty; (6) gross negligence; and (7) punitive damages. Defendant then filed the instant motion to dismiss, alleging that all Plaintiff's claims should be dismissed because they allege only conclusory facts that do not satisfy federal pleading standards.

Standard of Review

Because this Court has diversity jurisdiction over this matter, state law governs substantive issues, but federal law governs procedure. *Paine v. Jefferson Nat'l Life Ins. Co.*, 594 F.3d 989, 991–92 (8th Cir. 2010). Under Federal Rule of Civil Procedure 12(b)(6), a court may dismiss a complaint if it fails "to state a claim upon which relief can be granted." To avoid dismissal, a complaint must include "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In reviewing the complaint, the court construes it liberally and draws all reasonable inferences from the facts in the plaintiff's favor. *Monson v. Drug Enforcement Admin.*, 589 F.3d 952, 961 (8th Cir. 2009).

Discussion

I. Plaintiff has stated a negligence claim.

"In any action for negligence, a plaintiff must establish the defendant owed a duty of care to the plaintiff, the defendant breached that duty, and the defendant's breach proximately caused the plaintiff's injury." *Wieland v. Owner-Operator Servs., Inc.*, 540 S.W.3d 845, 848 (Mo. banc 2018) (citation omitted). "[M]edical device manufacturers have 'the duty to exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products.'" *Mack v. Stryker Corp.*, 748 F.3d 845, 849 (8th Cir. 2014) (quoting *O'Hare v. Merck & Co.*, 381 F.2d 286, 291 (8th Cir. 1967)).

Plaintiff's complaint alleges that Defendant represented its pelvic-mesh products, including those used on Plaintiff, were safe. Compl. at ¶ 39. But Plaintiff lists sixteen ways that Defendant's Products were not prudently designed and manufactured, including that it used polypropylene material—a "material that is biologically incompatible with human tissue" —and non-medical grade, counterfeit material illegally smuggled in from China to make the Products. *Id*. at ¶ 32. Defendants had a duty to all foreseeable plaintiffs to ensure the safety of its products. *Id.* at ¶ 27. Instead of so doing, Plaintiff alleges Defendant failed to adequately study the risks or knew that such risks could cause serious injuries to patients receiving the devices but ignored those risks in constructing its Products and marketing its Products as safe and effective, thereby breaching its duty of care to Plaintiff. *Id*. at ¶¶ 34–35, 40–41. Plaintiff's physician relied on Defendant's false representations about the efficacy of the Products when opting to use them on Plaintiff, and but for those representations, Plaintiff would not have consented to the implantation of the Products. *Id*. at ¶ 42–44. The Products injured Plaintiff. *Id*. at ¶ 40. Thus, Plaintiff factually establishes the elements of a negligence claim that is plausible on its face, and so her negligence claim remains.

II. Plaintiff has stated a claim for failure to warn her physician.

Next, Defendant claims that, under Missouri's learned-intermediary doctrine, Plaintiff has failed to state a claim for failure to warn under the strict-liability and negligence theories to the extent such claims rely on a duty to warn anyone other than Plaintiff's physician. This point is well-taken.

The elements of strict tort liability are fulfilled "if the product was in an unreasonably dangerous defective condition when put to a reasonably anticipated use, and the plaintiff was damaged as a direct result of such defective condition as existed when the product was sold." *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 791 (Mo. Ct. App. 2008) (emphasis omitted); Mo. Rev. Stat. § 537.760. A plaintiff may prove that a product is unreasonably dangerous due to an

inadequate or nonexistent warning. *Nesselrode v. Executive Beechcraft, Inc.*, 707 S.W.2d 371, 375, 384 (Mo. banc 1986). The key issue in a failure-to-warn case is whether the information included with the product "effectively communicates to the consumer or user the dangers that inhere in the product during normal use and the dangerous consequences that can or will result from misuse or abnormal use of the product." *Id*. at 382.

But under the learned-intermediary doctrine, a medical-device manufacturer satisfies its duty to warn by providing adequate warnings to the prescribing physician. *Mitchell v. Covidien Plc*, No. 4:14-CV-0636-FJG, 2015 WL 12804270, at *5 (W.D. Mo. Sept. 28, 2015) (citing *Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670. 671 (8th Cir. 1985)). Thus, to plead a viable failure-to-warn claim in a prescription-medical-device case in Missouri, the plaintiff must allege facts showing: "(1) that the defendant failed to warn the prescribing physician of a risk associated with the use of the product . . . and (2) that the failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff[s'] injury." *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1138 (8th Cir. 2014) (quoting *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1098-99 (5th Cir. 1991)) (applying Missouri law).

Because Defendant owed no duty to Plaintiff or the medical community at large, Plaintiff's claims for failure to warn must be dismissed to the extent they are premised on Defendant's failure to warn anyone other than Plaintiff's physician of the risks associated with the Products. But Plaintiff has adequately alleged that Defendant failed to warn her physician of the risks associated with the Products. Compl. at ¶¶ 72–84 (alleging failure to warn "Plaintiff's healthcare providers" and listing eighteen areas in which the warnings were deficient). Thus, the failure-to-warn strict-liability and negligence claims remain to that extent only.

III. Plaintiff has stated a claim for design defect and manufacturing defect.

Defendant also contends that Plaintiff's design-defect and manufacturing-defect claims

consist of only conclusory allegations, which are insufficient to meet federal pleading standards. This argument is without merit.

In addition to failure to warn, the unreasonably dangerous defective condition required to prove strict tort liability can also be a manufacturing defect or a design defect. *Nesselrode,* 707 S.W.2d at 382. A manufacturing defect "refers to the improper assembly of an individual product," and a design defect "refers to a product, by nature of its design, being unreasonably dangerous." *Smith,* 275 S.W.3d at 792; *Richcreek v. Gen. Motors Corp.*, 908 S.W.2d 772, 776 (Mo. Ct. App. 1995). Because there is "a very fine line between design and manufacturing defects," "subtle factual differences, when applied to a failure of a particular product, can appear as both a manufacturing and design defect." *Richcreek,* 908 S.W.2d at 776–77.

Plaintiff's complaint alleges that Defendant sold the Products in the ordinary course of business. Compl. at ¶ 18. Dr. Kephart implanted in Plaintiff those Products, which were in the same condition as they were when they left the Defendant's possession and used in the manner directed and expected by Defendant. *Id*. at ¶ 51. Plaintiff then lists eleven reasons why the design of these Products was unreasonably dangerous, including the use of polypropylene material—which is biologically incompatible with human tissue—and the use of non-medical grade, counterfeit material illegally smuggled in from China to make the Products. *Id*. at ¶¶ 48, 62–63. Because of these defects, Plaintiff suffered physical and mental injuries and pain and suffering; has undergone and will further undergo corrective surgery or surgeries; and has incurred medical expenses. *Id*. at ¶¶ 24, 54, 69.

Contrary to Defendant's assertion, Plaintiff has pled specific facts supporting the alleged design and manufacturing defects in this case. As for Defendant's argument that Plaintiff did not specify how the manufacturing defect differed from its original design, it is reasonable (and perhaps optimistic) to infer that Defendant's original design of the Products did not include nonmedical grade,

counterfeit materials. *See Pritchett v. Cottrell, Inc.*, 512 F.3d 1057, 1064 (8th Cir. 2008) (ruling that Missouri law permits a defect to be proven by circumstantial evidence "as long as the defect may be inferred without resort to conjecture and speculation."); *Gillan v. Wright Med. Tech. Inc.*, 396 F. Supp. 3d 844, 848 (E.D. Mo. 2019) (denying the defendant's motion to dismiss plaintiff's manufacturing-defect claim where the plaintiff alleged only that the device failed). Accordingly, these allegations, viewed in the light most favorable to Plaintiff, satisfy the federal pleading standards for stating design-defect and manufacturing-defect claims under Missouri law.

IV. Plaintiff has failed to state claims of breach of implied and express warranty.

Defendant claims that Plaintiff has failed to plausibly state claims alleging breach of implied and express warranty because she failed to identify any specific warranty Defendant made regarding the Products. Plaintiff argues she pled that Defendant marketed its Products as safe and effective. The Court finds Plaintiff's pleading insufficient to state a claim.

Under Missouri law, the elements of a breach-of-express-warranty claim are: (1) the defendant sold goods to the plaintiff; (2) the seller made a statement of fact regarding the kind or quality of those goods; (3) the statement was a material factor inducing the buyer to purchase the goods; (4) the goods did not conform to the statement of fact; (5) the nonconformity harmed the buyer; and (6) the buyer notified the seller of the nonconformity in a timely fashion. *Renaissance Leasing, LLC v. Vermeer Mfg. Co.*, 322 S.W.3d 112, 122 (Mo. banc 2010); Mo. Rev. Stat. § 400.2–313.1(a). The buyer of the product must give some type of a pre-suit notice to the seller to state an express breach of warranty claim. *Budach v. NIBCO, Inc.*, No. 2:14-CV-04324-NKL, 2015 WL 6870145, at *4 (W.D. Mo. Nov. 6, 2015). To establish a breach-of-implied-warranty claim, a party must prove (1) a merchant sold goods, (2) which were not "merchantable" at the time of the sale, (3) injury and damages to the buyer, (4) which were caused proximately or in fact by the defective nature

of the goods, and (5) notice to the seller of the injury. *Cobbins v. J.E. Dunn Constr. Co.*, No. 4:15-CV-0031-ODS, 2016 WL 6440139, at *3 (W.D. Mo. Oct. 28, 2016).

Here, Plaintiff's complaint alleges only that "Defendant made numerous representations about the quality, safety, and effectiveness of the devices, which formed warranties" and "expressly and impliedly warranted the Products to be of merchantable quality and to be safe and effective and fit for such uses." Compl. at ¶ 92–93. These allegations are wholly insufficient to support Plaintiff's breach-of-warranty claims. Not only does Plaintiff fail to identify any statement Defendant made regarding the Products, but she also fails to identify who made the statement, and when, where, or how this alleged representation was made to Plaintiff or her physician. Perhaps most importantly, Plaintiff fails to plead that Plaintiff personally saw or read any materials in which an express warranty was made. She also failed to allege any type of pre-suit notice to Defendant.

Moreover, Plaintiff's breach-of-implied-warranty claim is duplicative of Plaintiff's strict-liability claims. Under Missouri law, the difference between strict liability and implied warranty is conceptual since the liability imposed for either is based in tort. *See Witherspoon v. Gen. Motors Corp.*, 535 F. Supp. 432, 434 (W.D. Mo. 1982) ("(t)he [sic] liability imposed for breach of an implied warranty is of 'tort nature' and, in Missouri, the difference between 'strict liability' or 'implied warranty' is not one of substance.") (quoting *Matulunas v. Baker*, 569 S.W.2d 791, 794 (Mo. Ct. App. 1978)); *see also Keener v. Dayton Elec. Mfg. Co.*, 445 S.W.2d 362, 364 (Mo. 1969) ("Whether the words 'strict liability' or 'implied warranty' or both combined are used, the difference in Missouri would not be one of substance since our courts are clearly recognizing the tort nature of the liability imposed."). Thus, where, as here, Plaintiff's breach-of-implied-warranty claim is founded upon the same facts as her design-defect claim, the breach-of-implied-warranty claim must fail. Should discovery reveal new information making this claim viable, Plaintiff is free to seek

reconsideration.

For these reasons, Plaintiff's claims for breach of express and implied warranty are DISMISSED WITHOUT PREJUDICE.

V. Plaintiff cannot state a claim of gross-negligence.

Defendant argues that Plaintiff's gross-negligence claim must be dismissed because Missouri law does not recognize it as an independent claim. Plaintiff concedes as much. *See Decormier v. Harley-Davidson Motor Company Group, Inc.*, 446 S.W.3d 668, 671 (Mo. banc 2014) ("Missouri courts do not recognize degrees of negligence . . ."). Accordingly, Plaintiff's gross-negligence claim is DISMISSED WITH PREJUDICE.

VI. Plaintiff's punitive damages count remains as a dependent count.

Finally, Defendant claims that Plaintiff's punitive-damages count must be dismissed because there is no independent cause of action for punitive damages under Missouri law. True, Plaintiff cannot maintain a standalone count for punitive damages, but Missouri courts have allowed separate punitive damages counts to proceed so long as they incorporate by reference actual-damages claims. *See, e.g.*, *Harris v. Jungerman*, 560 S.W.3d 549, 555 (Mo. Ct. App. 2018) (allowing an independent count of punitive damages to proceed when it incorporated by reference other claims for actual damages). Because Plaintiff incorporated by reference all the paragraphs of her complaint in her punitive-damages claim, Compl. at ¶ 108, that claim is viable so long as her underlying claims remain.

Conclusion

Because Plaintiff has failed to sufficiently state claims of breach of express and implied warranty, those claims are DISMISSED WITHOUT PREJUDICE. Plaintiff's gross-negligence claim is DISMISSED WITH PREJUDICE, and her failure-to-warn claims remain only to the extent they relate to Defendant's failure to warn her physician of the risks associated with the Products. All other

claims remain. Plaintiff shall have until May 1, 2020, to file an amended complaint.

IT IS SO ORDERED.

Date: April 3, 2020

/s/ Greg Kays
GREG KAYS, JUDGE
UNITED STATES DISTRICT COURT